Exhibit A

AO 88B (Rev. 06/09) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Pennsylvania

Plaintiff v. In re Ethicon, Inc., Pelvic Repair System Products Liability Litigation *Defendant*	Civil Action No. MDL No. 2327 (If the action is pending in another district, state where: Southern District of West Virginia)

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Secant Medical, LLC, c/o CT Corporation System PA, Dauphin, 700 Park Ave, Perkasie, PA 18944-0

☒ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material:

See Attachment A

Place:	Date and Time:
c/o Roger Cameron, Kline & Specter, The Nineteenth Floor, 1525 Locust Street, Philadelphia, PA 19102	10/7/2013 10:00 AM

☐ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: 9/6/2013

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail, and telephone number of the attorney representing *(name of party)* Plaintiffs, P. Ann Trantham, Ann Trantham Law Office P.L.L.C., 5020 Montrose, Suite 300, Houston, TX 77007, patrantham@gmail.com, 713-757-2590, who issues or requests this subpoena, are:

Civil Action No. MDL 2327

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

☐ I served the subpoena by delivering a copy to the named person as follows: _____

_____

_____ on *(date)* _____ ; or

☐ I returned the subpoena unexecuted because: _____

_____

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of

$ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ _____

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed

information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

EXHIBIT A TO SUBPOENA FOR PRODUCTION OF DOCUMENTS TO SECANT MEDICAL, LLC

DEFINITIONS

1. For purposes of this subpoena and the Requests contained herein, the following terms shall have the following meanings:

a. "SECANT," "You," or "Your" refers to SECANT MEDICAL, LLC, and any of its predecessors in interest, successors in interest, parent-companies, subsidiaries, divisions, subdivisions, affiliates, officers, directors, employees, representatives, independent contractors, consultants, or agents, whether present or former, including attorneys and accountants.

b. "Ethicon, Inc.." refers to Ethicon, Inc.., and any of its predecessors in interest, successors in interest, parent companies, subsidiaries, divisions, subdivisions, affiliates, officers, directors, employees, representatives, independent contractors, consultants, or agents, whether present or former, including attorneys and accountants.

c. "Communication" means the transmittal of information (in the form of facts, ideas, inquiries, or otherwise).

d. "Concerning" means relating to, referring to, describing, evidencing, embodying, or constituting.

e. "Document" is defined to be synonymous in meaning and equal in scope to the usage of this term in Federal Rule of Civil Procedure 34(a), including, without limitation, electronic data or computerized data compilations including all information that serves to identify, locate, or link such material, such as file inventories, file folders, indices, and Metadata. This term also refers, without limitation, to the original and all copies, prior drafts and

translations, written, printed, typed, photostatic, photographed, recorded, or otherwise reproduced communications, data compilations, or representations of every kind, whether comprised of letters, words, numbers, pictures, sounds, or symbols, whether prepared by manual, mechanical, electronic, magnetic, photographic, or other means, as well as audio, video or other recordings of communications, oral statements, conversations, or events. Furthermore, this term includes, but is not limited to, any and all of the following: correspondence, notes, minutes, records, messages, memoranda, telephone memoranda, diaries, contracts, agreements, invoices, orders, acknowledgements, receipts, bills, statements, appraisals, reports, forecasts, compilations, schedules, studies, summaries, analyses, pamphlets, brochures, advertisements, news articles, tables, tabulations, financial statements, working papers, tallies, maps, drawings, diagrams, pictures, film, microfilm, microfiche, computer-stored or computer-readable data, computer programs, computer printouts, telegrams, telexes, facsimiles, tapes, transcripts, recordings, and all other sources or formats from which data, information, or communications can be obtained. A draft or non-Identical Copy is a separate document within the meaning of this term.

f. "Electronic data" or "data" means the original (or identical duplicate when the original is not available), and any non-Identical Copies of writings and data compilations in any form, and of every kind and description, including electronically stored information or "ESI", whether inscribed by mechanical, facsimile, electronic, magnetic, digital, or other means. Electronic data includes, but is not limited to, computer programs (whether private, commercial, or work-in-progress), programming notes or instructions, activity listings of electronic mail receipts and transmittals, output resulting from the use of any software program, including word processing files generated using programs such as Word or WordPerfect; spreadsheets and tables such as Excel or Lotus 123 worksheets; accounting application

data such as QuickBooks, Money, or Peachtree data; databases such as Access, Oracle, SQL Server data, or SAP; charts, graphs and outlines; electronic mail and other digital communications such as e-mail, voicemail and instant messaging; images and facsimile files; sound recordings such as .WAV and .MP3 files; video and animation such as AVI and .MOV files; contact and relationship management data such as Outlook and ACT; calendar and diary application data such as Outlook PST and blog entries; online access data such as Temporary Internet Files, History and Cookies; presentations such as PowerPoint and Corel Presentations; network access and server activity logs; project management application data; computer aided design/drawing files; backup and archival files such as VERITAS, Zip and .GHO; operating systems, source code of all types, peripheral drivers, PIF files, batch files, ASCII files, and any and all miscellaneous files and file fragments, regardless of the media on which they reside and regardless of whether said electronic data consists in an active file, deleted file or file fragment. Electronic data also includes any and all items stored on computer memories, hard disks, floppy disks, CD-ROMs, e-mail server stores such as Lotus Domino .NSF or Microsoft Exchange .EDB, removable media such as Zip disks, Jaz cartridges, Bernoulli Boxes and their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape, computer chips, including, EPROM, PROM, RAM and ROM, on or in any other vehicle for digital data storage and transmittal. Furthermore, the term electronic data includes the file, folder tabs and containers and labels appended to, or associated with, any physical storage device associated with each original and copy.

g. "Electronic media" means any magnetic or other storage media device used to record electronic data. Electronic media devices include, but are not limited to, computer memories, hard disks, floppy disks, CD-ROM, removable media such as Bernoulli Boxes

and their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape, computer chips, including, EPROM, PROM, RAM and ROM, or on or in any other vehicle for digital data storage and transmittal.

h. "Identical Copy" means:

i. A full and complete copy of the original Document that does not differ from the original paper Document because of highlights, comments, annotations, marks, transmission notations, underlining, marginalia, total pages, attachments, notes, markings or other alterations of any kind. Each such differing copy shall itself be considered an original paper Document and not an Identical Copy. For example, where there are two documents with identical content but one has highlighting and the other does not, in such a situation, the two documents shall not be considered identical.

ii. An electronic Document that is a copy of the original electronic Document including Metadata. Identical copies of the original electronic Document will generate the same MD5 Hash value. For example, and Identical Copy would include copies of the same Document saved on an individual custodian's local hard drive or an accessible network shared drive. An Identical Copy would not include copies of the same Document found in two individual custodians' produced Documents.

i. "Including" or "includes" means including, without limitation.

j. "Metadata" means: (i) information embedded in or associated with a native file that is not ordinarily viewable or printable from the application that generated, edited, or modified such native file which describes the characteristics, origins, usage and/or validity of the electronic file; and/or (ii) information generated automatically by the operation of a computer or other information technology system when a native file is

created, modified, transmitted, deleted or otherwise manipulated by a user of such system.

k. "Mesh" includes but is not limited to the following mesh products:

i. 6-mil Prolene Mesh (Secant Medical P/N: FSMK0009)

ii. 5-mil Prolene Mesh (Secant Medical P/N: FSMK0008)

iii. 3.5-mil Prolene Mesh (Secant Medical P/N: FSMK0129)

iv. 6-mil TVT Prolene Mesh – Clear (Secant Medical P/N: FSMK0138)

v. 6-mil TVT Prolene Mesh – Blue (Secant Medical P/N: FSMK0137)

vi. Vicryl #9 Mesh (Secant Medical P/N: FSMK0132)

vii. Vicryl #12 Mesh (Secant Medical P/N: FSMK0013)

viii. Woven Vicryl Mesh (Secant Medical P/N: FSMW0010)

ix. VHD Knit Mesh (Secant Medical P/N: FSMK0309)

x. Dyed UltraPro Knitted Mesh (Secant Medical P/N: FSMK0286)

xi. Undyed UltraPro Knitted Mesh (Secant Medical P/N: FSMK0286)

l. "Person" means any natural person or any business, legal, or governmental entity or association.

2. The following rules of construction apply to all discovery requests:

a. The terms "all" and "each" shall be construed as all and each;

b. The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope;

c. The use of the singular form of any word includes the plural and vice versa; and

d. Requests that are stated in the present tense include the past tense and those in the past tense include the present tense.

INSTRUCTIONS

1. Each Request refers to documents in the custody, control, and possession of SECANT ("SECANT MEDICAL, LLC"), or known to SECANT, as well as in the custody, control, and possession of or known to SECANT'S counsel, representatives, agents, servants, investigators, contractors, and consultants, and unless otherwise privileged, their counsel, employees, representatives, agents, servants, investigators, contractors, and consultants.

2. If any document responsive to these requests is unavailable, because it was lost, altered, deleted, or destroyed by SECANT or its agents, or for any other reason, SECANT shall fully identify the document and also state:

a. When and where it was lost, altered, deleted, or destroyed, or why it is otherwise unavailable;

b. The name and address of each person who lost, altered, deleted, or destroyed it, or who otherwise caused it to be unavailable;

c. The name and address of each person who directed, approved, or knew of its alteration, deletion, or destruction, and

d. The name and address of each person who has knowledge of this document.

3. If you cannot produce a document that is responsive to these requests for any other reason, please respond to the extent possible, stating each reason why you cannot respond in full.

4. These requests shall be deemed to be continuing, to the full extent required or permitted under the Federal Rules of Civil Procedure, so as to require supplementary production when SECANT or its agents obtain access, custody, possession, or control of any document not previously produced, which is responsive to any of these Requests.

5. Pursuant to FRCP 26(b)(5), any document falling within the scope of this Request that is withheld on the basis of a claim of privilege, work product, or any other ground is to be identified in writing and must include: a statement of the ground alleged for withholding such document; the Bates range of the document; its date; the identity of its author, recipients, and signatories; the type of document (e.g., letter); a summary of its contents; its present location; and, its custodian(s). Notwithstanding the assertion of an objection, any purportedly privileged document containing non-privileged matter must be disclosed with the purportedly privileged portion redacted, with the redacted portion indicated on the document itself and listed on the privilege log to be provided pursuant to this paragraph.

6. Documents are to be produced in full and in their unexpurgated form. Redacted documents shall not constitute compliance with these Requests, unless such documents are properly redacted pursuant to a valid claim of privilege or work product as set forth in paragraph 5 above.

7. All documents produced in response to these Requests shall be organized and labeled either to correspond with the number of the specific request to which the documents are responsive or shall be produced in the order, format, and manner in which they are kept in the usual course of business.

8. Unless otherwise set forth, the relevant time-period for each Request is from the beginning of time to the present.

DOCUMENTS TO BE PRODUCED

1. Policies, procedures, rules and/or guidelines regarding Your document and record management, including the retention, storage and/or destruction of relevant (or potentially relevant) documents for such time that there exists a reasonable expectation of foreseeable litigation in connection with such documents.

2. Any and all contracts, communications, invoices, purchase orders, agreements, or other documents between You and Ethicon, Inc., related to the sale of mesh for use in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

3. Communications, invoices, purchase orders, agreements, or other documents between You and Ethicon, Inc., related to the manufacture/fabrication/extrusion of mesh substances/materials used in mesh products, including but not limited to pelletized unpigmented and pigmented polypropylene resin (Type-F040-S), C4001, copoloymer resin, homopoloymer resin, and Mesh Roll Stock, used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

4. Any and all documents which relate to, refer to, or embody patents and patent applications for any mesh or substances/materials used in mesh products sold, manufactured, fabricated, or extruded by You including but not limited to the materials/substances of pelletized unpigmented and pigmented polypropylene resin (Type-F040-S), C4001, copoloymer resin, homopoloymer resin, and Mesh Roll Stock, used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

5. Any and all documents related to, refer to, or embody licensing agreements and/or manufacturing agreements for any mesh sold, manufactured, fabricated, or extrued by You

including but not limited to the materials/substances of pelletized unpigmented and pigmented polypropylene resin (Type-F040-S), C4001, copoloymer resin, homopoloymer resin, and Mesh Roll Stock, used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.by You to Ethicon, Inc.

6. Any and all documents related to, refer to, or embody company operating policies/procedures and/or protocols for any mesh sold by You to Ethicon. This request specifically includes documents containing information related to use of Your policies/procedures and/or protocols referencing International Organization for Standardization standards and/or guidelines, documents referencing quality control, biocompatibility, cytotoxicity, sterilization, winding, cleaning, knitting, batching, handling, storage and transportation of medical goods, cleaning, handling of materials used in mesh products sold to Ethicon, Inc., component scouring instructions, knitted fabric counts, thickness testing, ball burst testing, and elasticity testing.

7. Any and all documents related to, refer to, or embody regulatory rules and/or guidelines. This request specifically includes documents containing information related to your incorporation and utilization of U.S. Food and Drug rules, regulations or guidelines, including International Organization for Standardization (ISO) 10993, "Biological Evaluation of Medical Devices", guidance documents released by the FDA, Blue-Book Memorandum #G95-1, "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing", and standardization protocols/guidelines issued by the Organization for Economic Cooperation and Development (OECD), U.S. Pharmacopoeia (USP), and the ASTM International (formerly known as the American Society for Testing and Materials) for any mesh sold by You to Ethicon, Inc.

8. Any and all documents relating, referring to or embodying communications between You or any agent or consultant of Yours, and the FDA or any other foreign or domestic governmental agency, regarding the manufacture of mesh sold by You to Ethicon, Inc., and any material or component manufactured by a third party. This request specifically includes documents relating to FDA Enforcement Inspection Reports (EIR) and all documents relating, referring to or embodying any warnings, objections or criticisms by the FDA and/or any foreign regulatory authority concerning the manufacture of any mesh sold by You to Ethicon, Inc., including audits, notices or inspections related thereto.

9. Any and all documents related to the creation or development of design specifications for the manufacture of mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence. This request specifically includes documents containing information on any specifications for all materials manufactured by You and any material or component manufactured by a third party.

10. Any and all documents concerning any proposed or implemented changes to the design specifications for the manufacture of mesh sold or to be sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence. This request specifically includes documents containing information on any proposed or implemented changes to the design specifications for all materials manufactured by You and any material or component manufactured by a third party.

11. Any and all documents related to the manufacturing specifications of mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

12. Any and all documents related to the manufacturing protocols for mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

13. All documents concerning the manufacturing process for any component, part, or material which was sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence. This request specifically includes documents containing information on any manufacturing process for all materials manufactured by You and any material or component manufactured by a third party, including but not limited to:

a. Structure and components;

b. Spacing and size of the mesh's pores;

c. Coating of the mesh;

d. Heating of the mesh components or finished mesh

e. Type of weave;

f. Stiffness of mesh;

g. Chemical, textile, and metallurgical components and composition;

h. Packaging; and/or

i. Sterilization

14. All documents concerning any proposed or implemented changes in the manufacturing process for the manufacture of the mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence, including, but not limited to:

a. Structure and components;

b. Spacing and size of the mesh's pores;

c. Coating of the mesh;

d. Heating of the mesh components or finished mesh

e. Type of weave;

f. Stiffness of mesh;

g. Chemical, textile, and metallurgical components and composition;

h. Packaging; and/or

i. Sterilization

15. Any and all documents related to the testing, inspection, and/or analysis of the mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

16. Any and all documents related to the testing, inspection, and/or analysis of the mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence to determine whether it conformed to Ethicon, Inc.'s design and/or manufacturing specifications.

17. All Material Safety Data Sheets (MSDS) and Performance-Based Occupational Exposure Limits (PB-OELs) in your possession related to Ethicon Inc.'s mesh products and their component parts.

18. Any and all documents related to the inspection, analysis, and quality control of any component, part, or material used in the mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence, including but not limited to:

a. Vendor History Logs;

b. Engineering change orders;

c. Technical Report Advisory Sheets;

d. Certificates of Conformance;

e. Articles of First Inspection (AFI);

f. Component Services Lab Test Request form;

g. Component Services Lab Test Reports;

h. Deviation Authorization Forms (DRs); and/or

i. Material Reject Records (MRRs).

j. Shop order transaction audit reports; and/or

k. Testing.

19. Any and all documents related to any agreement by Ethicon, Inc., to accept mesh manufactured by You that deviated from Ethicon, Inc.,'s design and/or manufacturing specifications.

20. Any and all documents relating to quality assurance and/or quality control protocols, procedures and/or analyses and/or changes to the manufacturing process of any component, part, or material used in mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence. This request specifically includes documents containing information on any quality assurance and/or quality control protocols, procedures and/or analyses and/or changes to the manufacturing process for all materials manufactured by You and any material or component manufactured by a third party, including but not limited to quality control inspection reports, audits, compliance documents.

21. Any and all documents related to the Design Freeze, the Design and Development Plan, Design Input, and/or the Verification/Validation Test Plan prepared by Ethicon, Inc., for

mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

22. Any and all documents that relate to Ethicon, Inc.'s efforts to discuss, confirm, understand, or assess whether You manufactured mesh in accordance with its design and/or manufacturing specifications.

23. Any and all documents regarding the identity of any third parties or vendors which participated in the design or manufacture of any component, part, or material used in mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence. This request specifically includes documents containing information on any third party or vendor for all materials manufactured by You and any material or component manufactured by a third party, including but not limited to the North American Science Associates, Inc. (NAMSA).

24. Any and all documents pertaining to any third parties or vendors which participated in the design or manufacture of the mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence including, but not limited to design specifications, manufacturing specifications, protocols, quality assurance and/or quality control protocols, contracts, delivery and shipping schedules, testing, and pricing. This request includes, but is not limited to, documents that reference, contain, or relate to communications between You and any third parties or vendors which participated in the design or manufacture of the mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

25. Any and all standards utilized or relied upon by You or any third party or vendor in the design or manufacture of the mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

26. Any and all documents related to inspection, evaluation and certification of Your quality management system by National Science Foundation (NSF) International Strategic Registrations.

27. Any and all documents that relate to inspections, audits, or evaluations of Your manufacturing facilities, equipment, processes, or procedures, by employees, agents, contractors, and/or representatives of Ethicon, Inc.

28. Any and all documents, minutes or notes of meetings relating to, or in any way pertaining to, the efficacy of mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

29. Any and all documents, minutes or notes of meetings relating to, or in any way pertaining to, risk or safety discussions, questions, or concerns associated with the mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

30. Any and all documents, minutes or notes of meetings relating to, or in any way pertaining to, adverse events associated with the mesh sold by You to Ethicon, Inc.., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

31. Any and all documents pertaining to confidentiality, non-compete, and/or non-disclosure agreements between You and Ethicon, Inc.

32. Any and all documents related to payments made by Ethicon, Inc. to You for the purchase of mesh and/or other material sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence

33. Documents sufficient to identify Your quarterly and yearly gross and net revenues from the sale of mesh and/or other material by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

34. Documents sufficient to identify what percentage of Your quarterly and yearly total sales were composed of sales made by You to Ethicon, Inc., for the years You sold mesh to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

35. Any and all documents evidencing any indemnification agreements between You and Ethicon, Inc.